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Introduction

This report describes the progress on this project on staff recruitment and training, IRB and other administration and subject recruitment to 8/31/10 which was when funds from the first seedling grant were fully expended on a no-cost extension. A second consecutive seedling grant is continuing the same research project but with a randomized controlled trial.

Body

Key Research Accomplishments

Staff Recruitment and Training

Kristen Reinhardt was recruited as the research assistant/research coordinator for this project and began full time effort on the project as of March 9, 2009. She was trained in her duties which include IRB administration, subject recruitment, telephone screening, informed consent, subject scheduling, administration of questionnaires, acquisition of electrocardiographic recording techniques and urinary sample collection, and preliminary data management and analysis.

Jennifer Johnston, a Northeastern University clinical psychology graduate student and certified yoga instructor was recruited as the project leader and yoga instructor on this study. Her role includes preparing the yoga curriculum, instructing the yoga classes, managing IRB documentation and performing final data analysis

IRB Administration

An IRB protocol was drafted and reviewed by a representative of the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO). The IRB protocol was submitted on 3/31/09 to the IRB of Brigham and Women's Hospital and was approved on 5/8/09. The protocol was then submitted to the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO) on 5/11/09. Following a response to a request for clarifications and revisions from that office on 6/30/09, IRB approval from HRPO was received on 8/12/09. The IRB protocol was submitted on 3/16/2010 for Continuing Review to the IRB of Brigham and Women's Hospital and was approved on 3/22/2010.

Protocol Development

The yoga treatment protocol and manual has been completed in consultation with yoga instructors in the region with experience in instructing yoga to military veterans. The treatment protocol and manual were approved by the IRB on 8/14/09 and by the HRPO on 8/12/09.

Additional Administration

We have submitted an application to the Harvard Catalyst Center for Clinical Investigation for support of the proposed project, which will include partial support of assay costs and use of ambulatory outpatient clinical treatment space. Following a response to a receipt of a request for clarifications on this application, formal support of the study was confirmed in September, 2009.

Following IRB approval, an application was submitted for a Certificate of Confidentiality, which was formally approved on 10/9/09.

The study protocol was submitted to Clinical Trials.gov and was registered on that site as of 8/27/09.

Recruitment

Preliminary research was conducted to identify a list of potential organizations from which military veterans might be recruited and letters of support from those organizations were acquired. Advertising in public media was initiated for subject recruitment in early September, 2009.

As of 8/31/10 we have received 147 inquiries from potential participants, we have conducted 105 telephone screens and we have enrolled 26 subjects who have all signed informed consent.

Protocol Execution

As of 8/31/10, across two cohorts we have run 10 subjects through the full intervention and all outcome measures (including long term follow-up). From the first cohort, we had one subject who did not fully complete endpoint outcome measures or long term follow-up measures.

Progress Relevant to Statement of Work

All tasks within the Statement of Work have been executed later than anticipated. This was largely due to the fact that although the grant was initiated on 9/25/09, substantial effort on the project, and disbursement of grant funds, did not begin until March of 2009. However, the project is now underway and recruitment and enrollment are continuing.

Reportable Outcomes

For the 10 subjects for whom the pre- and post-intervention data is available on the Clinician Administered PTSD Scale (CAPS), the average pre-intervention total score was 70.4 ± 21.6 S.D. and the average post-intervention total score was 43.3 ± 25.1 S.D. A paired t-test indicates a p-value of 0.02. On the

Average CAPS subscale pre- and post-treatment scores, and p-values, for REXEperiencing, Avoidance and Hyperarousal were as follows:

REXEperiencing:	19.5 ± 7.8	8.3 ± 8.2	$p=0.06$
Avoidance:	30.8 ± 16.9	13.8 ± 7.3	$p=0.08$
Hyperarousal:	22.0 ± 6.8	19.7 ± 14.6	$p=0.01$

Other acquired outcome measures are still under analysis.

Conclusions

Although the project is delayed relative to the grant start date, reasonable progress has been made on study startup, recruitment and intervention delivery. Our preliminary data of a single group trial indicate that statistically significant improvements have been observed in the primary PTSD outcome measures, particularly in hyperarousal. We anticipate similar improvements in our continuing randomized controlled trial.

References

Yoga as an Intervention for Post-Traumatic Stress Disorder (PTSD) in Military Personnel, J. Johnston, S.B.S. Khalsa, International Journal of Yoga Therapy, 20 (Suppl 1):28, 2010.

Appendices

Published abstract

#19 Yoga as an Intervention for Post-Traumatic Stress Disorder (PTSD) in Military Personnel

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Keywords: yoga, post-traumatic stress disorder

Objective: The effectiveness of yoga practice has led to its use as a therapeutic treatment for a variety of specific medical and psychological disorders. This single-arm pilot study is designed to ascertain whether yoga is a feasible and effective intervention to reduce PTSD symptoms in service men and women with PTSD.

Methods: Active-duty or veteran military service men and women are being recruited through

Veterans' organizations, newspaper ads, and word-of-mouth for this study. This study is a ten-week, twice-weekly, 90-minute yoga intervention, with a 15-minute daily home yoga practice. Outcome measures include self-report and clinician-administered questionnaires, yoga compliance and sleep diaries, EKG recordings, and 24-hour urine samples. The primary outcome measure is the Clinician-Administered PTSD Scale (CAPS), which is administered pre- and post-intervention.

Results: The first cohort of subjects ($n = 8$) has completed the intervention, and seven have completed all post-intervention follow-up measures. For the seven subjects for whom the pre- and post-intervention data is available for the CAPS, the mean pre-intervention total score was 77.3 ($SD = 28.6$), with a mean post-intervention total score of 51.1 ($SD = 27.6$). A paired t test indicates a p value of 0.06, when comparing pre- and post-intervention CAPS scores of symptoms *in the past month*. When comparing pre-intervention CAPS scores with post-intervention scores of symptoms *in the past week*, the p value was 0.02. Mean session attendance was 10.34 ($SD = 7.5$), with five of eight subjects completing 16 or more sessions. No adverse events occurred.

Conclusions: Given the recruitment, intervention delivery, and retention of the subjects, results demonstrate that yoga is a feasible and promising intervention with military service men and women with PTSD. Also, there was a clinically and statistically significant reduction in PTSD symptoms as ascertained by pre-post CAPS scores regarding symptoms *in the past week*. Although pre-post CAPS scores *in the past month* were not significant, it's possible these scores will reach significance by study end.